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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

February 12, 2002

Ref: 2002-DAL-WL-10

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Clinton Howard,
President/Chief Executive Officer
Royal Body Care, Inc./
MPM Medical, Inc.
2301 Crown Court
Irving, Texas 75038

Dear Mr. Howard:

This letter concerns drugs and medical devices marketed by your firm under the MPM Medical, Inc. label. Investigators of the Food and Drug Administration (FDA) conducted an inspection of your firm, MPM Medical, Inc., at the above referenced address on September 5/10, 2001. Based on the information, labels, and promotional materials obtained during that inspection, the marketing of these products violates the Federal Food, Drug, and Cosmetic Act (the Act) as described below.

DRUG PRODUCTS:

MPM WOUND & SKIN CLEANSER
MPM ANTIMICROBIAL WOUND & SKIN CLEANSER
MPM NORMLSHIELD™ MOISTURE BARRIER

Based on their respective labels and labeling (including a promotional brochure titled "MEDICAL PRODUCTS FOR BETTER LIVING"), these three products are offered for over-the-counter (OTC) use. The first of these is intended for treating wounds through cleansing the affected area. The second is for use in treating wounds through cleansing the affected area while "destroy[ing]" microorganisms on the skin, and the third is for skin protectant use. Since these products are intended to mitigate, treat, or prevent disease and/or to affect one or more of the body's structures or functions, they are "drugs" as defined by section 201(g) of the Act.

In addition, these products are "new drugs," as defined by section 201(p) of the Act and, because neither is the subject of an FDA-approved new drug application (NDA) as required by section 505(b) of the Act, their marketing in the United States violates section 505(a) of the Act as follows:

MPM WOUND & SKIN CLEANSER

This product is labeled as containing "Poloxamer 188," and as an OTC "Wound . . . Cleanser." The labeling further represents this product as useful in "Soften[ing] Necrotic Tissue for **easy removal**," and in "Aid[ing] Debridement" in treating "Pressure Ulcers. . . Venous Stasis Ulcers . . . Dehisced Wounds [and] Partial Thickness Wounds." Such representations cause this product to be a "new drug" because we are not aware of any scientific evidence showing that it is generally recognized as safe and effective for these uses. This product is not subject to FDA's OTC Drug Review since no other product so formulated and labeled has ever been commercially marketed to qualify for evaluation under this Review. Further, the agency has never proposed that such a product be included in this Review.[1] As noted above, this product is not the subject of an approved NDA; therefore, it may not be legally marketed at this time.

MPM ANTIMICROBIAL WOUND & SKIN CLEANSER

This product is labeled as containing "Benzethonium Chloride" as the sole "Active Ingredient." The labeling further represents this product as an "Antimicrobial Wound & Skin Cleanser," that is "Proven Effective Against . . . MRSA (Methicillin Resistant Staphylococcus Aureus) . . . VRE (Vancomycin Resistant Enterococus [sic]) . . . Pseudomonas Aeruginosa . . . Escherichia Coli . . . Aspergillus Niger. . Streptococus [sic] Pyogenes [and] Staphylococcus Aureus," . . . that it "destroys

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[1] Several antimicrobial ingredients and a surfactant, poloxamer 188, were evaluated under FDA's OTC Drug Review for use as a wound cleanser, i.e., "a safe nonirritating liquid preparation (or product to be used with water) which assists in the removal of foreign material from *small superficial wounds* and does not delay wound healing" (emphasis added). (See 39 FR 33102.) However, none of the labeled uses described above, which cause *MPM WOUND & SKIN CLEANSER* to be a "new drug," is currently subject to evaluation under the OTC Drug Review. The tentative final monograph (TFM) for OTC "First Aid Antiseptic Drug Products" published in the Federal Register of July 22, 1991 (56 FR 33644). That TFM combines into one category (i.e., OTC first-aid antiseptics) OTC "skin wound cleansers," "skin wound protectants," and "skin antiseptics." All three of these initial categories are described in the report on "OTC Topical Antimicrobials" from the Advisory Review Panel, which published under the Review in the Federal Register of September 13, 1974 (39 FR 33102), and in the (first) TFM for these drug products, which published in the Federal Register of January 6 1978 (43 FR 1210). The 1991 TFM actually removed from further consideration under this monograph all "skin wound cleansers" making no antiseptic claims. At that time the agency advised that non-antiseptic "skin wound cleansers" would be evaluated separately in a future rulemaking, which is still pending.

indicated microbes," that it "Softens Necrotic Tissue for **easy removal,**" and "Requires **no rinsing**." By identifying microorganisms by name, the labeling suggests that the product is useful in preventing the diseases caused by them. The labeling also claims that this antimicrobial drug product does not require rinsing with water and may remain on the skin for an indeterminate time, suggesting that it provides continuous antimicrobial effectiveness while it remains on the skin. The labeling also represents this product as useful in removing necrotic tissue and other debris from infected wounds of unspecified severity. Such representations cause this product to be a "new drug" because we are not aware of any scientific evidence showing that it is generally recognized as safe and effective for these uses. This product is not subject to FDA's OTC Drug Review since no other product so formulated and labeled has ever been commercially marketed to qualify for evaluation under this Review. Further, the agency has never proposed that such a product be included in this Review. As noted above, this product is not the subject of an approved NDA; therefore, it may not be legally marketed at this time.

MPM NORMLSHIELD™ MOISTURE BARRIER

This product is labeled as containing "Dimethicone" as the sole "Active Ingredient." The labeling represents this product as an OTC drug and that it is useful as a "Skin Protectant" to, among other things, provide "soothing relief from . . . ITCHING" caused by "incontinence related skin problems," to "shield[ ] the skin from . . . drainage from wounds," and to "Protect[ ] skin around tracheotomies." The labeling further represents the product "Contains **Aloe Vera** which helps heal urine scalds and denuded skin." Such representations cause this product to be a "new drug" because we are not aware of any scientific evidence showing that it is generally recognized as safe and effective for these uses. This product is not subject to FDA's OTC Drug Review since no other product so formulated and labeled has ever been commercially marketed to qualify for evaluation under this Review. Further, the agency has never proposed that such a product be included in this Review. As noted above, this product is not the subject of an approved NDA; therefore, it may not be legally marketed at this time.

In addition to the above violations, the labeling for *MPM NORMLSHIELD™ MOISTURE BARRIER* identifying the ingredient, "Aloe Vera," as effective in healing urine scalds and denuded skin, establishes this ingredient is an "active" drug ingredient as defined in 21 CFR 201.66(b)(2). Since it is not so declared on the label, this product is misbranded under section 502(e)(1)(A)(ii) of the Act.

MEDICAL DEVICES:

MPM Excel-Gel Aloe Vera/Glycerin Wound Gel
MPM Regenecare™ Wound Gel

Under the Act, these products are considered devices because labeling (including the promotional brochure) indicates use of these products in diagnosis of disease, or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or intended to affect the structure or any function of the body of man, and/or treatment of a medical condition.

The law requires that manufacturers of devices obtain FDA marketing clearance or approval of their products from the FDA before they can offer them for sale. This helps protect the public health by ensuring that newly introduced medical devices are safe and effective, and will perform as intended/labeled. A guidance document and labeling requirements for marketing these devices can be found at http://www.fda.gov/cdrh/.

Our records indicate you did not obtain marketing clearance or approval before marketing *MPM Excel-Gel Aloe Vera/Glycerin Wound Gel* for the management of surgical wounds and dehisced incisions, or with labeling claims that aloe feeds macrophages and fibroblast cells for the management of these wounds. Additionally, our records indicate you did not obtain marketing clearance or approval before marketing *MPM Regenecare™ Wound Gel* with lidocaine or with the claims of pain reduction, the promotion of granulation and epitheliazation, or to assist the body to heal itself.

Because you do not have marketing clearance from the FDA, your products are being marketed in this country in violation of the Act. In legal terms, these products are adulterated under section 502(f)(1)(B), in that they are Class III devices under section 513(f) and they do not have approved applications for premarket approval (PMA) in effect pursuant to section 515 or approved applications for investigational device exemption (IDE) under section 520(g). Accordingly, your products are adulterated under the Act because you did not submit information that shows your devices are safe and effective.

The *MPM Regenecare™ Wound Gel* is misbranded under section 502(o) of the Act, in that a notice or other information respecting the modification to the device and the new intended use of the device was not provided to FDA as required by section 510(k) of the Act, and 21 CFR 807.81(a) (3)(i) and (ii), respectively.

Furthermore, the MPM *Excel-Gel Aloe Vera/Glycerin Wound Gel* is misbranded under section 502(o) of the Act, in that a notice or other information respecting the new intended use of the device was not provided to the FDA as required by section 510(k) and 21 CFR 807.81(a)(3)(ii). Therefore, your products are misbranded under the Act because you did not submit information showing your devices are substantially equivalent to other devices that are legally marketed.

Additionally, as a specification developer of devices, you have failed to meet the requirements for assuring device quality under current good manufacturing practice (CGMP) conditions. These requirements are set-out in the Quality System Regulation (QSR), Title 21, Code of Federal Regulations (21CFR) Part 820. Our investigators determined that your firm has failed to establish a Quality System setting forth the policy and objectives for, and a commitment to, quality. Established Procedures are not in place, for example, for internal audits, contract manufacturer audits, management responsibility and review, and implementation of corrective and preventative action where necessary.

A Form FDA-483, Inspectional Observations, was issued to and discussed with Mr. Paul R. Miller, President, MPM Medical Inc. at the inspection conclusion. I have attached a copy of that form for your information. Note the "Annotations" on that form, indicating Mr. Miller's commitment to correct the deviations. Failure to comply with the applicable requirements of the QSR renders your devices adulterated under section 501(h) of the Act.

There are many FDA requirements pertaining to the manufacture and marketing of drugs and devices. This letter pertains only to premarket approval/clearance of the products, CGMP controls for drugs, and the QSR for your devices, and does not address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for drug and device manufacturers on the Internet at http://www.fda.gov.

In summary, the inspection found serious violations of the law that, unless corrected, may result in FDA taking regulatory action without further notice to you. These actions may include, but are not limited to seizure of regulated products, injunction against further marketing of the products, or for medical devices, assessment of civil money penalties. Also, other Federal Agencies are advised of warning letters issued by FDA to regulated firms, in order that they may consider this information when awarding government contracts.

It is necessary for you to take immediate action to correct the violations. Please let this office know in writing within fifteen (15) working days, from the date of receipt of this letter, what steps you have taken to correct the problems. We also

request that you explain in your response how you plan to prevent similar violations in the future.

If you find that you need more time to complete corrective actions, let us know why and when you expect to complete your corrections. Please direct your response to James R. Lahar, Compliance Officer, at the above letterhead address.

Sincerely,

Michael A. Chappell
Dallas District Director

MAC:jrl

Enclosure